

MAR 27 2008

*Vinion v. Amgen*  
No. 05-36121

CATHY A. CATTERSON, CLERK  
U.S. COURT OF APPEALS

B. FLETCHER, Circuit Judge, dissenting:

I agree with the majority holding that Appellants' contract claims were properly dismissed by the district court because the written Study Agreement between Dr. Whitehouse and Appellee Immunex Corp., now Amgen Inc. ("Amgen"), does not require that Amgen provide the study drug free of charge to Appellants after the limited duration of the clinical trial, and because Appellants' oral contract claims are barred. It is also clear that Dr. Whitehouse was not Amgen's actual agent.

However, I disagree with the majority's conclusion that "no action or inaction" by Amgen "would have led the Appellants to a reasonable belief that Dr. Whitehouse was [Amgen's] agent." Maj. Op. at 3. It is possible that based on the record a jury could find that Amgen "intentionally or by want of ordinary care cause[d]" Appellants to believe Dr. Whitehouse to be Amgen's implied agent. *See* Mont. Code Ann. § 28-10-103(1). Because it remains an open question, for a jury to decide, whether Dr. Whitehouse had implied authority to commit Amgen to provide Appellants the study drug after the limited duration of the clinical trial,

summary judgment denying Appellants' state law tort claims was inappropriate. Accordingly, I respectfully dissent.

Summary judgment cannot be affirmed when a genuine issue of material fact remains in dispute. Here, our central inquiry is whether, under Montana law, a genuine issue of material fact remains in dispute as to the question of implied agency. In *Butler v. Domin*, the Montana Supreme Court held that it is improper to grant summary judgment when the principal fails to put the third party on notice as to the employment relationship between itself and the alleged agent. 15 P.3d 1189 (Mont. 2000). Because Appellants never saw the Study Agreement before signing the Informed Consent document at the beginning of the study, the Informed Consent document was the only document that gave Amgen the opportunity to put Appellants on notice of Dr. Whitehouse's "independent contractor" status. It did not do so.

The majority notes that the Informed Consent document states that the study is "under the direction" of Dr. Whitehouse. Maj. Op. at 3. The majority then concludes that because nothing in the Informed Consent document indicates that Dr. Whitehouse would be acting under the direction of Amgen, Appellants should be on notice that Dr. Whitehouse was not Amgen's agent. However, the fact that the Informed Consent document, which Amgen drafted, is silent on the key issue

of whether Dr. Whitehouse was in a position to commit Amgen cuts against the majority's conclusion.

In *C.A.R. Transp. Brokerage Co., Inc., v. Darden Restaurants, Inc.*, 213 F.3d 474 (9th Cir. 2000), this court, applying California law defining ostensible agency (which is the same under Montana law; *compare* Mont. Code Ann. § 28-10-103 with Cal. Civ. Code § 2300), found that a frozen shrimp seller was an ostensible agent “based on the silence of the principal alone,” where, as here, the principal transacts business with a party solely through the agent. In the present context, while it is true that the nature of clinical studies requires pharmaceutical companies to let the doctors deal with patients, it is incumbent upon the companies to make its role and the physician's role clear at the outset.

Instead of taking precautions to clarify that Dr. Whitehouse was not Amgen's agent, the Informed Consent document minimizes Amgen's role in the study, mentioning Amgen only in the context of discontinuing the study, as a supplier of the study drug, as the source of funding for the study, and as an authorized recipient of medical records. By way of contrast, many provisions of the Informed Consent document could have led Appellants to draw the reasonable inference that Dr. Whitehouse was the sole communicator of Amgen's position and thus its implied agent. The Informed Consent document:

- 1) held Whitehouse out to be “Sponsor” and “Principal Investigator;”
- 2) directed participants to Whitehouse (or study staff) “to explain any words or information that you do not clearly understand;”
- 3) directed participants to discuss costs of medical care during the experiment with Whitehouse;
- 4) directed participants to notify Whitehouse “as soon as possible if you decide to withdraw consent;”
- 5) advised that Whitehouse would notify participants if the study was discontinued and advise participants of available treatments that may be of benefit;
- 6) directed participants to ask all medical questions related to the study or a research related inquiry to Whitehouse, providing his phone number and pager number;
- 7) was signed only by the clinical trial subject, the person conducting the Informed Consent discussion, an investigator, and a witness—notably, not by Amgen.

In accord with the Informed Consent document, Appellants could rely only on their interactions with Dr. Whitehouse. In this light, Dr. Whitehouse’s testimony that he thought he was in a position to communicate credibly to the patients on behalf of Amgen is critical. While he may not create apparent agency in himself, simply because Amgen transacted business with Appellants solely through him, implied agency can be found “based on the silence of the principal alone” in failing to put Appellants on notice to the contrary. *C.A.R. Transp. Brokerage Co., Inc.*, 213 F.3d 474.

In his deposition, Dr. Whitehouse stated “[I] was just passing on the information from Ann Hayes” of Amgen, and noted that he was in a good position

to act as a credible conduit between Amgen and Appellants because Appellants “very much so” trusted him. In his affidavit to the district court, Dr. Whitehouse stated he “communicated [Amgen’s] promise to the study participants, including Mr. Vinion and Mr. Riddle, particularly since they both inquired as to what would happen if the [study drug] proved beneficial for them; both of them communicated to me that they viewed participation in the study more favorably knowing that the drug would continue to be supplied to them if it proved to be beneficial[.]”

The record also contains letters from Dr. Whitehouse to Appellants Vinion and Riddle. Dr. Whitehouse wrote to communicate that he had been in contact with Amgen and that “[a]pparently Amgen is not going to follow through with Immunex’s original verbal promise to continue drugs if it was helpful.” He also offered that “[i]f I get any further word I will be happy to pass that on as quickly as I see it...” This communication reinforces Appellants’ notion that just as Dr. Whitehouse had communicated Amgen’s promise, he now communicated Amgen’s repudiation of that promise.

Finally, the majority states that Amgen cannot be held liable for Dr. Whitehouse’s statements that “compassionate use” in this context to mean free provision of the study drugs after the limited duration of the clinical trial. He made that statement based in part upon his knowledge of a previous Amgen trial in

Southern California where Amgen did provide free drugs to trial participants indefinitely on a “compassionate use” basis at the conclusion of that trial. The majority concludes that the inconsistency in provision of free drugs after the conclusion of its trials “has no bearing on whether [Amgen’s] conduct toward Appellants left them with the reasonable belief that Dr. Whitehouse was [Amgen’s] agent.” Maj. Op. at 4. However, to the contrary, the evidence of the Southern California trial further underscores the credibility of Appellants’ belief in Dr. Whitehouse’s promise that Amgen would provide the study drug free of charge to Appellants after the trial and could help lead a jury to the conclusion that his communication of that promise was an act of an implied agent.

For the foregoing reasons, I would reverse the summary judgment denying Appellants’ state law tort claim and remand to the district court for further proceedings.